

### REMARKS

As an initial matter, Applicants wish to thank Examiners Li Zheng and Ashwin Mehta for the insightful telephonic interview of July 18, 2007, with Applicants' representatives, Karen Magri and Alice Bonnen, and Murray Spruill and Leslie Henry, representatives of Biolex, Inc., the assignee of U.S. Patent No. 6,815,184. During this interview the non-statutory obviousness-type double patenting rejection over U.S. Patent No. 6,815,184 was discussed. In a follow-up interview on July 26, 2007 between Applicants' representative, Karen Magri and Examiner Zheng, this double-patenting rejection was again discussed. No agreement was reached during either of these interviews.

Claims 1-40 are pending in this application. The additional comments provided herein were not provided earlier as Applicants truly believe the double patenting rejections of the pending claims are improper and should have been withdrawn in view of the arguments already of record. Entry of these remarks into the record of the present application is respectfully requested in order to further prosecution or to place the application in better condition for appeal.

Reconsideration of the claims is respectfully requested in view of the following remarks. The issues raised in the Office Action dated February 28, 2007 are addressed individually below in the order presented therein.

#### **Double Patenting.**

I. The Action states that claims 1-10, 12-31 and 33-40 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1 and 22-25 of U.S. Patent No. 6,815,184 (hereinafter "the '184 patent"). In addition, the Action states that claims 11 and 32 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of the '184 patent in view of Dieryck *et al.* (*Transfus. Clin. Biol.* 2:441-447 (1995)). This rejection is respectfully traversed.

As an initial matter, Applicants note that the '184 patent has only 17 claims. Thus, there are no claims 22-25 in the '184 patent. During the interviews with the Examiners, Applicants' representatives confirmed with the Examiner that claims 1 and 17 of the '184 patent were meant to be referred to in this double patenting rejection and

not claims 22-25. Accordingly, in the following discussion, Applicants will refer to claims 1 and 17 of the '184 patent.

The MPEP Is Clear that the Reason for a Double Patenting Rejection is to Prevent the Unjustified Timewise Extension of the Right to Exclude Granted by a Patent

Applicants respectfully submit that the present double patenting rejection is improper. MPEP Section 804 indicates that :

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity of the term of the patent. The public policy behind this doctrine is that:

The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent, but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

MPEP (Rev. 5, Aug. 2006), Section 804, page 800-11.

As further noted in the discussion that follows, "double patenting exists when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982)." Clearly, in the present case, the extension of patent term is not an issue. The present application has an effective filing date of August 12, 1997 and if issued into a patent would expire August 13, 2017, well before the expiration date of the '184 patent.

The prohibition against the unjust extension of patent term is further reiterated in Section 804 of the MPEP, page 800-21, which sets forth that a nonstatutory double patenting rejection "is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

The section of the MPEP that governs the present situation is MPEP 804.03 IV, pages 800-37 through 800-39, regarding rejections under 35 USC 102 and 103 and double patenting. Form paragraph 7.21.01 *Provisional Rejection, 35 USC 103(a), Common Assignee or at Least One Common Inventor* should be applied to the present situation. The present application and the '184 patent do not have a common assignee or are not subject to a joint research agreement as defined by The CREATE Act. The present application and the '184 patent do share a common inventor.

MPEP form paragraph 7.21.01 indicates that in the present case the claims of the '184 patent should have been provisionally rejected under 35 USC 103(a) as obvious over the present application, which was copending during the prosecution of the '184 patent. As stated in the form paragraph, "[b]ased upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application." MPEP, page 800-38.

As noted in the discussion that follows, this form paragraph should be used by an examiner to provisionally reject claims not patentably distinct from the disclosure in a copending application having an earlier U.S. filing date and also having either a common assignee or at least one common inventor. As noted on page 800-39, "if an application has a later effective U.S. filing date than a conflicting issued patent, the examiner should consider making a rejection in the application, based on the patent, under 35 U.S.C. 102(e) or 102(e)/103(a) using form paragraph 7.15.02 or 7.21.02. The discussion distinguishes the present situation from the situation where the application and the patent are subject to a joint research agreement under The CREATE Act.

The fact overlooked by the Examiner in the present application is the fact that the present application has an effective filing date that is **earlier than** the filing date of the '184 patent. The priority date for the present application is August 12, 1997, whereas the priority date for the '184 patent is July 31, 2000. Thus, the '184 patent is not prior art for purposes of double patenting under 35 U.S.C. 102 or 103. The present application is the earlier filed application. Further, the present product claims were filed with the originally filed U.S. application in 1998 (09/132536) and were pending at the time the '184 patent was under prosecution. Thus, the proper rejection that could have

been made by the examiner was to reject the '184 patent application over the present application. Applicants note that the '184 patent was determined by the USPTO to be both novel and non-obvious over the prior art including the PCT counterpart of the present application (PCT/US98/16683; WO 99/07210), which was specifically considered during this patentability evaluation.

In conclusion, based upon the procedures set forth in the MPEP there is no double patenting issue for the present application in view of the '184 patent. Accordingly, the double patenting rejection should be withdrawn.

The CREATE Act Safe-Harbor Provisions Do Not Apply to the Present Application

As noted above, the present application and the '184 patent are not commonly assigned, nor subject to a joint research agreement, as provided by The CREATE Act. Thus, the double patenting concerns brought about by the CREATE Act are not an issue in the present application. The CREATE Act provides a simple means of extending the "safe harbor" provisions of current law that treats inventions of a common owner similarly to inventions made by a single person. To promote collaborative research within organizations, Congress enacted the Patent Law Amendments of 1984, which, inter alia, exempt "common owner" inventors from the application of certain types of prior art and information in obviousness determinations, subject to the exercise of the same double patenting principles that apply when inventions are made by a single inventor. Importantly, "[p]atents issued under this Act shall be enforceable in the same manner, to the same extent, and for the same term as when patents are issued to a common owner or are subject to common assignment. The doctrine of "obviousness-type double patenting," a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent's right to exclude, shall apply to such patent." H.R. REP. 108-425, page 5.

As set forth in Department of Commerce RIN 0651-AB76:

Once an examiner has established a *prima facie* case of obviousness under 35 U.S.C. 103(a), the burden is on the applicant to overcome the rejection by invoking 35 U.S.C. 103(c) as amended by the CREATE Act. . . To overcome such a rejection via the CREATE Act, the applicant must provide a statement in compliance with §1.104(c)(4) to the effect that the prior art and the claimed invention were made by or on the

behalf of parties to a joint research agreement, within the meaning of 35 U.S.C. 103(c)(3), which was in effect on or before the date the claimed invention was made, and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. . If the applicant disqualifies the subject matter relied upon by the examiner in accordance with the CREATE Act and the procedures set forth in this final rule, the examiner will treat the application under examination and the 35 U.S.C. 102(e), (f), or (g) prior art as if they are commonly owned for purposes of 35 U.S.C. 103.

Federal Register Vol. 70, No. 177, 54259, 54261.

Thus, parties who seek to benefit from the CREATE Act waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection. A double patenting rejection is authorized where an applicant invokes the new provisions of 35 U.S.C. 103(c), even though there is neither a common inventor nor a common patent owner. Rule 1.109(b).

As discussed in the MPEP and in the CREATE Act, double patenting rejections may arise as a result of the amendment to 35 U.S.C. 103(c) by the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). Congress recognized that this amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting rejections between applications not owned by the same party (see, H.R. Rep. No. 108-425, at 5,6 (2003)). For purposes of double patenting analysis, the application or patent and the subject matter disqualified under 35 U.S.C. 103(c) as amended by the CREATE Act will be treated as if commonly owned.

Congress recognized that this amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting between applications not owned by the same party. See H.R. Rep. No. 108-425, at 5-6 (2003). Therefore, the Office is providing the following guidelines for double patenting rejections based upon a patent or application that is not commonly owned but was disqualified under 35 U.S.C. 103(c) as resulting from activities undertaken within the scope of a joint research agreement, which will be incorporated into the next revision of the MPEP.

Federal Register Vol. 70, No. 177, 54259, 54261.

However, this new category of double patenting created by the CREATE Act does not apply to the present application. Applicants are not seeking to benefit from the provisions provided by the CREATE Act. Furthermore, Applicants cannot take advantage of the provisions of the CREATE Act since there was no joint research agreement in place between the assignee of the present application and the assignee of the '184 patent. Accordingly, double-patenting under the CREATE Act does not apply to the present application and the rejection should be withdrawn.

Applicants further note that the MPEP section addressing the requirements of a double patenting rejection states that an "[o]bviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a **commonly owned patent**, or a **non-commonly owned patent but subject to a joint research agreement** as set forth in 35 U.S.C. 103(c)(2) and (3), when the issuance of a second patent would provide **an unjustified extension of the term** of the right to exclude granted by a patent." MPEP § 804(II)(B)(1) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001) and *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000)) (emphasis added). The present application and the '184 patent are not commonly owned, nor are they subject to a joint research agreement. Further, there is no unjustified extension of term in this case (the term of protection for the present application will expire at least 3 years prior to that of the '184 patent). Thus, the fundamental purpose for which the judicially created doctrine of obviousness-type double patenting was intended, i.e., to prevent the unjustified extension of the term of the right to exclude granted by a patent (which purpose is repeated throughout the MPEP), is not present in this case (See, MPEP § 804, § 804 (II), § 804(II)(B) and § 804(II)(B)(1)).

Additionally, the MPEP states:

If the provisions of 35 U.S.C. 103(c)(1) apply to the commonly owned conflicting inventions of different inventive entities or if the provisions of 35 U.S.C. 103(c)(2) apply to non-commonly owned inventions subject to a joint research agreement and thereby obviate the obviousness rejection(s), double patenting rejection(s) should be made (or maintained) as appropriate. **If, however, it is determined that the provisions of 35 U.S.C. 103(c) do NOT apply** because the inventions

were not commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, or because the claimed invention did NOT result from activities undertaken within the scope of a joint research agreement as required by 35 U.S.C. 103(c)(2) and (3), and there is evidence of record to indicate that a patent or application is prior art against the application being examined, the examiner should make (A) any appropriate double patenting rejection(s), and (B) the appropriate prior art rejection(s) under 35 U.S.C. 102 and/or 35 U.S.C. 103 in the application being examined.

MPEP § 804.03(IV) (emphasis added). Again, none of these fact patterns identified as appropriate for a double patenting rejection are found in the instant case. The provisions of §103(c) do not apply and the '184 patent is not prior art against the present application.

The same scenarios that are discussed in MPEP § 804.03(IV) (discussed in the preceding paragraph) are presented in Chart IIB in § 804 of the MPEP (marked copy enclosed herewith at Tab A). Chart IIB is a flow chart providing an outline of the treatment of applications with conflicting claims. If one follows the path for "different inventive entities, at least one common inventor and no common assignee" (middle of the chart) and then follows the path for "no joint research agreement" (all of which are the circumstances of the present application), this chart shows that a double patenting rejection is appropriate when the reference application or patent is prior art against the patent application at issue. It is specifically noted in Chart IIB that the term "AND" is used between the different rejections to be made. The use of "AND" is clearly intentional as "AND/OR" is used in another section of Chart IIB (see the path for "currently commonly owned→ different inventive entities"). Thus, the drafters of this section of the MPEP clearly understood the difference and deliberately chose to use "AND" under the particular circumstances where the application and the application/patent have different inventive entities, at least one common inventor, no common assignee, and no joint research agreement. As stated previously, since the '184 patent does not qualify as prior art against the present application, these rejections as outlined in Chart IIB cannot be made. Thus, Applicants respectfully submit that the requirements for a proper double patenting rejection as set forth in the MPEP are not met in this case, and therefore, the present double patenting rejection is improper.

II. The Action states that claims 1-10, 12-31 and 33-40 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over Claims 1 and 22-25 of pending Application Serial No. 10/873,846 (hereinafter the '846 application).

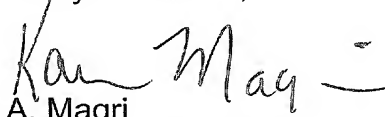
As the Examiner points out, this is a provisional rejection because no claims have issued in the case of the '846 application. Applicants respectfully note that the '846 application has been abandoned as of August 14, 2007. Continuation Application No. 11/778,480 was filed July 16, 2007. Thus, this rejection is believed to be mooted, and Applicants respectfully request its withdrawal.

**Conclusion.**

The points and concerns raised by the Examiner having been addressed in full, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested. Should there be any remaining concerns, the Examiner is encouraged to contact the undersigned attorney to expedite the prosecution of this application.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of \$1020.00 as the fee for a three-month extension of time. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,


  
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Katie Wu  
Date of Signature: August 28, 2007



Attorney Docket No.: 5051-337DVCT3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Stomp et al.  
Application No.: 10/677,441  
Filed: October 2, 2003  
For: *Genetically Engineered Duckweed*

Confirmation No.: 9042  
Group Art Unit: 1638  
Examiner: Li Zheng

Date: August 28, 2007

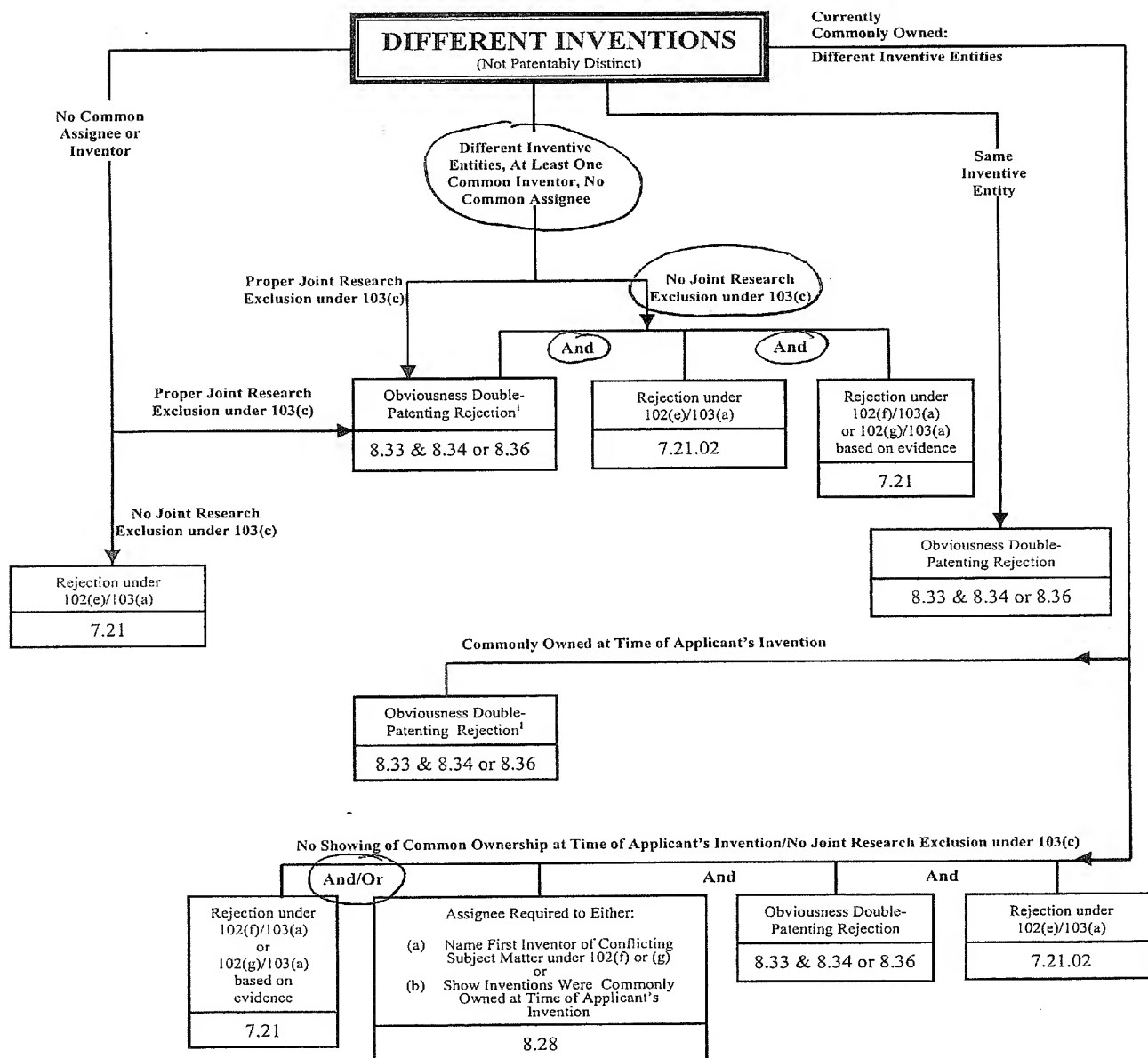
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TAB A

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# **CONFLICTING CLAIMS BETWEEN AN APPLICATION AND A PATENT**

CHART II-B



<sup>1</sup> Where the reference is available as anticipatory prior art, a rejection should be made under 102(e).